

Claims

Sub B
1. A solid non-effervescent compressed dosage form comprising an ibuprofen medicament and a carrier material comprising a compressible filler component combined with a disintegrating component wherein the ibuprofen medicament is present to an extent of 35% or more by weight of the dosage form, characterised in that the carrier material includes an alkali metal carbonate or bicarbonate in an amount such that the dosage form has a crushing strength in the range 6.5-15Kp and a disintegration time of less than 10 minutes, provided that the ibuprofen medicament does not contain a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

2. A dosage form according to claim 1 wherein the ibuprofen medicament is in the form of a salt of ibuprofen.

3. A dosage form according to claim 2 wherein the ibuprofen medicament is the sodium salt of racemic ibuprofen.

Sub B
4. A dosage form according to ^{Claim 1} ~~any one of claims 1 to 3~~ comprising a filler component and a discrete disintegrant component.

5. A dosage form according to ^{Claim 1} ~~any one of claims 1 to 4~~ comprising 5-15% w/w alkali metal carbonate or bicarbonate.

6. A dosage form according to ^{Claim 1} ~~any one of claims 1 to 5~~ wherein the alkali metal carbonate or bicarbonate comprises sodium carbonate or sodium bicarbonate.

Sub B
7. A dosage form according to claim 6 comprising sodium carbonate or bicarbonate in a weight ratio to the ibuprofen medicament of 1:2 to 1:10.

Sub B
8. A dosage form according to ^{Claim 1} ~~any one of claims 1 to 7~~ wherein the compressible filler component comprises one or more of microcrystalline cellulose, lactose and mannitol.

Claim
9. A dosage form according to ~~any one of claims 1 to 8~~ wherein the disintegrant comprises ~~one or more of croscarmellose sodium and sodium starch glycolate~~.

Claim 1
10. A dosage form according to ~~any one of claims 1 to 9~~ in the form of a compressed tablet.

Sub 3/5
11. The use of an alkali metal carbonate or bicarbonate in a carrier material including a compressible filler component combined with a disintegrating component, said carrier material being arranged for admixture with an ibuprofen medicament under substantially dry conditions and then for compression into a solid non-effervescent dosage form wherein the ibuprofen medicament comprises 35% or more by weight of the dosage form, the dosage form having a crushing strength in the range 6.5-15Kp and a disintegration time of less than 10 minutes.

12. The use according to claim 11 wherein the ibuprofen medicament is in the form of the sodium salt.

Claim 11
13. The use according to ~~either one of claims 11 and 12~~ wherein the carrier material is adapted for direct compression with the ibuprofen medicament into a tablet.

Claim 11
14. The use according to ~~any one of claims 11 to 13~~ wherein the solid dosage form comprises the sodium salt of ibuprofen together with a carrier material comprising microcrystalline cellulose and sodium carbonate or bicarbonate.

Claim 11
15. The use according to ~~any one of claims 11 to 14~~ wherein carrier material comprises 45-60% microcrystalline cellulose, 2-10% croscarmellose sodium and ~~2-20% sodium carbonate or bicarbonate~~.

Sub 6/7
16. A method of obtaining an onset-hastened analgesic and/or anti-pyretic response comprising the administration of a non-effervescent compressed solid dosage form comprising 35% or more by weight of an ibuprofen medicament together with a carrier material comprising a compressible filler component combined with a disintegrating component and an alkali metal carbonate or bicarbonate, the dosage form having a crushing strength in the range 6.5-15Kp and a disintegration time of

less than 10 minutes, provided that the ibuprofen medicament does not include a calcium salt of ibuprofen in combination with an alkali metal salt of ibuprofen.

17. A method according to claim 16 wherein the dosage form has a crushing strength in the range 8-12Kp, at a compression force in the range 100-140MPa.

claim 15

5 *Sub 15* 18. A method according to either one of claims 15 and 16 wherein the solid dosage form has a disintegration time in the range 1-5 minutes.

claim 16

19. A method according to any one of 16 to 19 wherein the dosage form is in the form of a directly compressed tablet comprising 40-85% w/w sodium salt of ibuprofen and 5-15% w/w sodium carbonate or bicarbonate.

10 20. A process to prepare a non-effervescent solid dosage form comprising an ibuprofen medicament present to an extent of 35% or more by weight of the dosage form and a carrier material comprising a compressible filler component combined with a disintegrating component, characterised by combining the carrier material incorporating an alkali metal carbonate or bicarbonate with the ibuprofen medicament to form a homogeneous solid mixture under substantially dry conditions optionally with other tableting excipients and compressing the mixture into one or more solid dosage forms having a crushing strength in the range 6.5-15Kp and a disintegration time of less than 10 minutes.

20 21. A process according to claim 20 wherein the ibuprofen medicament is a salt of racemic ibuprofen.

claim 20

22. A process according to either one of claims 20 and 21 wherein the carrier material comprises a inert diluent component.

claim 20

25 23. A process according to any one of claims 20-22 wherein the dosage form is prepared by direct compression of a powder mixture of the ingredients and does not include any pre-granulation stage.

claim 20
24. A process according to ~~any one of claims 20-23~~ wherein the ratio of the alkali metal carbonate or bicarbonate to compressible filler component is in the range 2:1 to 1:10 parts by weight.

claim 20
25. A process according to ~~any one of claims 19-24~~ wherein the ratio of ibuprofen medicament to the carrier material is in the range 2:1 to 1:2 parts by weight and the carrier material comprises 5-20% w/w sodium carbonate or bicarbonate.

10 26. A solid formulation having a layer comprising a composition comprising an ibuprofen medicament together with a carrier material, the ibuprofen medicament being present to an extent of 35% or more by weight of the composition and the carrier material comprising a compressible filler component combined with a disintegrating component characterised in that the carrier material comprises an alkali metal carbonate or bicarbonate in an amount such that the composition is capable of compression to provide a layer having a crushing strength in the range 6.5-15Kp and
15 a disintegration time of less than 10 minutes.

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B's**all
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